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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/127,624 08/03/98 PONCE DE LEON F 002076-007

HM12/1012

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EXAMINER

WILSON, M

ART UNIT

PAPER NUMBER

1633

DATE MAILED:

10/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Applicati n No.

09/127,624

Applicant(s)

PONCE DE LEON ET AL.

Examiner

Michael Wilson

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-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,7,8 and 29-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,7,8 and 29-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Applicant's arguments filed 8-8-01, paper number 15, have been fully considered but are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 1, 4, 5, 7, 8 and 29-40 remain pending and under consideration in the instant office action.

Priority

The effective filing date for claims 1, 4, 5, 7, 8 and 29-40 is 8-4-97.

Claim Rejections - 35 USC § 112

1. Claims 1, 4, 5, 7, 8 and 29-40 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of culturing avian PGCs comprising maintaining the avian PGCs for at least 14 days in culture comprising (i) isolating a pure population of PGCs from an avian; and (ii) culturing the pure population of PGCs in media comprising LIF, bFGF, IGF and SCF in amounts sufficient to maintain said PGCs for at least 14 days in tissue culture, does not reasonably provide enablement for culturing the PGCs for at least 14 days in media comprising "growth factors in amounts sufficient to maintain said PGCs for at least 14 days" as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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Claims 1, 4, 5, 7, 8 and 29-32 are directed toward a method of culturing a pure population of avian PGCs in a culture medium for at least 14 days. Claims 33-40 are directed toward a purified population of avian PGCs in culture media such that the PGCs are maintained for at least 14 days. Claims 1, 4, 5, 7, 8, 31-35 and 37-40 remain not enabled as broadly claimed for reasons of record.

The state of the art at the time of filing was that pure populations of avian PGCs had been cultured for 5 days in the presence of LIF, bFGF and IGF (Chang, 1995, Cell Biol. International, Vol. 19, pages 143-149; page 143, col. 2, 2nd paragraph through page 144, col. 2, 2nd full paragraph). However, a population of avian blastoderm cells comprising PGCs had been maintained for 160 days using bFGF, IGF, SCF and LIF (Pain of record, page 2340, col. 1, line 9; page 2340, col. 1, 4th and 5th full paragraphs; page 2345, col. 2, line 10; Simkiss of record, 1994, MacLean, ed., Animals with novel genes, Transgenic birds, Cambridge Univ. Press, Cambridge England, NY, NY, pages 106-137; page 111, Fig. 4.1, top panel).

The specification teaches culturing a pure population of avian PGCs for at least 14 days using growth medium comprising LIF, bFGF, IGF and SCF. The specification does not teach any other combination of growth factors that enable maintaining a pure population of avian PGCs for at least 14 days.

Claims 1, 4, 5, 7, 8, 31-35 and 37-40 remain rejected for reasons of record because the specification does not enable maintaining a pure population of PGCs in culture for at least 14 days using media comprising "growth factors in amounts sufficient to maintain said PGCs for at least

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fourteen days” as broadly claimed. The only method taught in the specification or the art at the time of filing (Pain of record) that results in maintaining PGCs in culture for at least 14 days requires culture media comprising LIF, bFGF, IGF and SCF. Therefore, the claims should be limited to media comprising LIF, bFGF, IGF and SCF in amounts sufficient to maintain said PGCs for at least fourteen days.

Applicants argue that one of ordinary skill in the art at the time the invention was made would have been able to identify other combinations of growth factors that are able to maintain a pure population of PGCs in culture for at least 14 days without undue experimentation.

Applicants argument is not persuasive. Given the state of the art (that a pure population of PGCs had not been cultured for 14 days and that an impure population of PGCs had been cultured for at least 14 days in the presence of LIF, bFGF, IGF and SCF (Pain of record)), taken with the guidance provided in the specification (maintaining a pure population of avian PGCs using media comprising LIF, bFGF, IGF and SCF for 14 days), one of ordinary skill in the art at the time the invention was only have been able to maintain a pure population of PGCs in culture for at least 14 days using growth media comprising LIF, bFGF, IGF and SCF. The amount of experimentation required to determine other combinations of growth factors that enable maintaining a pure population of avian PGCs for at least 14 days would be undue because of the vast number of growth factors and combinations thereof required to test and because there may no other combination of growth factors that provides such an effect. Therefore, the specification is only

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enabled for maintaining pure populations of avian PGCs for at least 14 days using media comprising LIF, bFGF, IGF and SCF.

Applicants argue that US Patent 5,821,121 and 5,942,435 have method claims that do not require the specific combination of growth factors required to culture cells for a specified period of time. Therefore, applicants argue that the patent office should be willing to offer broader claim for pioneering culturing methods that are not limited to the specific combination of growth factors required to culture the cells for the specified period. Applicants argument is not persuasive. It cannot be determined how such a conclusion was drawn in '121 and '435, particularly regarding the state of the art, the arguments provided and the post-filing evidence. The issued claims to which applicants refer may have been allowed based on evidence of more than one combination of growth factors that were adequate to maintain the cells for the specified time period. Therefore, applicants argument is not persuasive because the fact pattern in '121 and '435 does not parallel the fact pattern in the instant application.

Claims 32 and 38 are not enabled for reasons of record because the specification does not teach any feeder cells that provide growth factors in amounts sufficient to maintain PGCs for at least 14 days. Applicants argue that the specification contemplates transfecting feeder cells to express the desired growth factors. Applicants argument is not persuasive. First, the claims are not limited to transfected feeder cells. Second, applicants have not provided any evidence (correlative or otherwise) that feeder cells produce the amounts of the growth factors required to have the desired effect. Therefore, the mere statement that cells can be transfected to produce the

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growth factors required to maintain a pure population of PGCs for at least 14 days is not adequate to enable feeder cells that supply growth factors in amounts that maintain a pure population of avian PGCs for at least 14 days.

Double Patenting

2. Claims 1, 4, 5, 29-31, 33, 36, 37, 39 and 40 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,156,569, Dec. 5, 2000 for reasons of record. Applicants request to hold this rejection in abeyance until indication of allowable subject matter is acknowledged.

3. Claims 1, 7, 8, 33, 34 and 35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,156,569, Dec. 5, 2000 in view of Pain (Pain et al., 1996, Development, Vol. 122, pages 2339-2348) for reasons of record. Applicants request to hold this rejection in abeyance until indication of allowable subject matter is acknowledged.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Tracey Johnson, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-2982.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 305-0196.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson



MICHAEL C. WILSON
PATENT EXAMINER